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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/697,089	10/26/2000	John Bertin	07334-136001	3454

7590

12/13/2001

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EXAMINER

BUGAISKY, GABRIELE E

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 12/13/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/697,089

Applicant(s)

ROBISON ET AL.

Examiner

Gabriele E. BUGAISKY

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_.

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 12 and 18, drawn to constructs containing nucleic acids encoding CARD-12 and a method of making protein using the constructs, classified in class 435, subclass 69.1.
- II. Claims 8-10, drawn to CARD-12 polypeptide, classified in class 530, subclass 350.
- III. Claim 11, drawn to an antibody specific to CARD 12, classified in class 530, subclass 387.9.
- IV. Claims 13-14, drawn to a method for detecting the presence of a CARD-12 polypeptide, classified in class 435, subclass 7.1.
- V. Claim 15, drawn to a composition comprising a compound, which binds to CARD-12, classified in class 530, subclass 300.
- VI. Claims 16-17, drawn to a method of detecting nucleic acids encoding CARD-12, classified in class 435, subclass 69.1.
- VII. Claims 19-20 and 22, drawn to methods of identifying ligands of CARD-12, classified in class 435, subclass 7.4.
- VIII. Claims 21 and 23, drawn to a method of modulating activity of a CARD-12 protein, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be

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used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be either purified from natural sources or made by chemical synthesis such as the Merrifield procedure.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. An antibody is encoded by an entirely different gene than the protein which the antibody recognizes. It would place an undue burden on an Examiner to examine unrelated inventions.

Inventions I and IV, I and VII and I and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different DNA constructs are not disclosed as useful in an assay of protein activity or modulation of protein activity.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The role of the nucleic acid is to encode protein, while that of the ligand is to bind to protein.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

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product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used to make a protein by recombinant means.

Inventions II and III, II and V and III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The protein apparently has activity in regulating apoptosis, while the antibody binds to the protein and the ligand modulates activity of the protein; furthermore, the primary structure of a CARD-12 reveals nothing about the primary structure of any antibody or ligand that binds to it.

Inventions II and IV and II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used to generate antibodies for detection of the protein in tissue samples

Inventions II and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions a method of affecting protein activity does not require a purified protein.

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Inventions II and VI, III and VI and V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. Neither an encoded protein nor an antibody directed to that protein nor a ligand of the protein is disclosed as capable of use in a method of nucleic acid hybridization.

Inventions III and IV, and III and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used for immunoaffinity purification of CARD-12.

Inventions III and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The method of Group VIII does not require the use of a purified antibody; a antibody specific for CARD-12 may have no role in a method of modulating protein activity.

Inventions V and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

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§ 806.05(h)). In the instant case the ligand can be used for purification of CARD-12 by affinity chromatography.

Inventions IV and VI and IV and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. A method of detecting a protein has no role in a method of detecting a nucleic acid by hybridization nor does it have a role in modulating protein activity.

Inventions IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions has different effects. The invention of Group IV reveals the presence of a CARD-12 homolog, whereas the invention of Group VII is a screening assay for a compound that binds to a CARD-12.

Inventions V and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the ligand can be used for purification of CARD-12 by affinity chromatography.

Inventions V and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

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functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. A process of identifying a chemical compound in does not define the compound.

Inventions VI and VII and VI and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. A method of detecting a nucleic acid by hybridization has no role in methods of protein biochemistry.

Inventions VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions has different effects. The invention of Group VI is a screening assay for compounds that bind to a CARD-12 homolog, whereas the invention of Group VII is a method for modulation of CARD-12 homolog activity.

If Group VIII is elected, further restriction is required, between methods using compounds that modulate gene expression and methods using compounds directly modulate CARD-12 protein activity. These are methods utilizing patentably distinct compositions, which share no common structure and function; thus an election of this further restriction is not to be considered an election of species.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized

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divergent subject matter and their search required for any one of the Groups is not coextensive with that of another, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Gabriele E. Bugaisky, Ph.D. whose telephone number is (703) 308-4201. The Examiner can normally be reached from 8:15 AM to 12:15 PM on Mondays and from 8:15 AM to 1:15 PM on other weekdays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher S. F. Low, can be reached at (703) 308-2923.

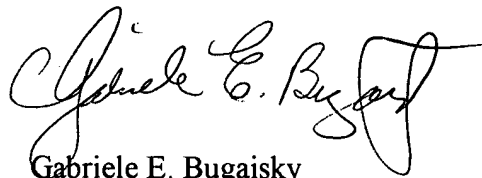
Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script, appearing to read "Gabriele E. Bugaisky".

Gabriele E. Bugaisky  
Patent Examiner  
December 12, 2001

**GABRIELLE BUGAISKY**  
**PATENT EXAMINER**